

MONTANA LEGISLATIVE HISTORY

Chapter 307 19 67

Bill H 455 S _____ Original bill & history ☒ c

H. Committee on Public Health, Wel....

Hearing Date(s) 2-7 ☒ c

_____ c

_____ c

_____ c

Date Out _____ c

S. Committee on Judiciary

Hearing Date(s) 2-20 ☒ c

_____ c

_____ c

_____ c

Did this bill originate in an interim committee? ☐ Yes ☐ No

Committee _____

Report _____

1967
House

Public Health, Welfare & Safety COMMITTEE

40th Legislative Assembly

Bill No.	Subject Matter	Date In	Hearing Date	Comments	Date Out	Committee Action
House Jnt. Res. No. 26 Teepie	Urging Allocation of Funds for Vets. Hosp. at Fort Harrison	1 '21	1 '31 2 '2		2 '3	Do Pass
House Jnt. Res. No. 27 Teepie	Construction of V.A. Domiciliary Unit at Ft. Harrison	1 '21	1 '31 2 '7		2 '8	Do Not Pass
House Jnt. Res. No. 28 -- McCulloch	Establishing Adequate & Permanent National Cemetery System for Military Personnel	1 '21	1 '31 2 '7		2 '8	Do Pass
358 -- Christiansen	Permitting Payment of Fine in Lieu of Liquor License Suspension	1 '21	1 '26 2 '7		2 '8	Do Not Pass
439 -- Delano	Providing Honorarium for Veterans Who Have Served in Vietnam	1 '21	1 '31		2 '8	Do Not Pass
450 -- Schye	10% Reduction in Case Lots of Liquor	1 '21	2 '7		2 '8	Do Not Pass
455 -- Bollinger	Revising Uniform State Food, Drug & Cosmetic	1 '21	2 '7		2 '8	Do Pass, As Amended

PUBLIC HEALTH, WELFARE & SAFETY COMMITTEE MINUTES

The Public Health, Welfare & Safety Committee met in Room 119 at 5:35 p.m., Tuesday, February 7, 1967. All committee members were present except Lee, who was excused: Chairman Crum presided.

House Bill 455: Representative Gordon E. Bollinger, principal sponsor, said that the purpose of the bill is to update our present pure food and drug law and create greater uniformity with the Federal Food, Drug, and Cosmetic Act, and with similar acts of other states. Mr. C. W. Brinck, Director, Environmental Sanitation, State Board of Health, and Mr. V. E. Sloulin, Chief Sanitarian, State Board of Health, spoke in favor of the bill, and Mr. Brinck presented two amendments which they were recommending (attached). Dr. John W. McMahan, physician from Helena, and representing the Montana Medical Association and the Lewis & Clark Medical Association, explained the proposed amendment concerning hallucinogenic drugs would make it a state offense to traffic in these drugs. Mr. Roderic R. Gudgel, Executive Secretary of the Montana State Pharmaceutical Association, stated his association was very much interested in this bill, and in regard to the proposed amendment on hallucinogenic drugs, said that it covers intra-state traffic and would provide control of manufacturing, possessing, selling, purchasing, prescribing, administering, dispensing or compounding any such drug (attached). The witnesses were excused. Mr. Delano moved that HB 455 "Do Pass, As Amended": motion was seconded and passed.

House Bill 233: Proponents -- Representative John B. Willits, principal sponsor of the bill, said that it is one that is needed in the interest of public health and safety. Representative Walter J. Ulmer stated that he is a strong proponent of the bill and urged its passage. Mr. Raymond E. Graham, representing the Great Falls Smeltermen, spoke for passage of the bill (statement attached). Mr. Tom Ryan, of Great Falls, representing the Montana Farmer Union, urged the passage of the bill to provide some protective regulation of blood banks, particularly in rural Montana. Mr. James W. Murry, of Helena, Director of Montana State AFL-CIO, rose in support of HB 233. Mr. George Kalafatich, international representative of the International Union of Miners, Millmen and Smeltermen, also rose in support of the bill. Dr. William G. Shull, of Great Falls, Medical Director of the American Red Cross in Montana, favored the bill and stated his willingness to answer any questions concerning this legislation. Opponents -- Dr. E. C. Segurd, a Billings pathologist, stated he was not strictly an opponent of the bill, and whereas he felt the bill was written with good intent, he did question its necessity at this time since 95% of the blood used in Montana was obtained either from the American Red Cross blood services or from sources licensed by the National Institute of Health. The other 5% was obtained from so-called walking donors in the smaller communities, who maintain a list of donors. Dr. E. W. Koneman, Chairman of the Committee of Blood of the Montana Medical Association, said he was concerned what the bill might do to the smaller communities in isolated areas, and that the proposed regulations might mean they would no longer be able to have a blood bank. Dr. John W. McMahan, surgeon from Helena, representing the Montana Medical Association, also expressed concern for the problems of the smaller communities under such a law, and explained that blood donors are not paid for their blood, but that a charge was made for typing, processing and administering the blood. Mr. Russ Hegland, representing the Montana Medical Association, said that the Legislative Committee and the Executive Committee of the M.M.A. voted not to support HB 233. Following the question period, witnesses were excused. Chairman Crum appointed Delano, Hall and Steele as a subcommittee to study HB 233.

HJR 27: Representative Randall D. Teeple, principal sponsor, stated that the resolution asking for a domiciliary is to augment the hospital at Fort Harrison and would not be in competition with the one at Columbia Falls or the Old Soldiers' Home. Mr. Chester K. Shore, representing the Veterans of World War I, said they did not wish to jeopardize the Soldiers' Home. Witnesses were excused. Mr. White moved that House Joint Resolution 27 "Do Not Pass"; the motion was seconded and passed.

That House Bill No. 455 be amended as follows:

Following line 19, page 35 of the original bill, insert two new sections to read as follows:

"Section 24. Hallucinogenic Drugs--Prohibitions. It shall be unlawful for any person to manufacture, possess, have under his control, sell, purchase, prescribe, administer, dispense or compound any hallucinogenic drug or any preparation which has a physiological effect similar to that produced by any hallucinogenic drug unless authorized so to do by the state board of health.

"Section 25. Hallucinogenic Drugs--Penalties.

(a) Whoever violates any provision of section 24 shall upon conviction be fined not more than two hundred and fifty dollars (\$250) and be imprisoned not less than two (2) or more than five (5) years. For a second offense, or if, in case of a first conviction of violation of any provision of section 24, the offender shall previously have been convicted of any violation of the laws of the United States or of any state, territory or district relating to hallucinogenic drugs, the offender shall be fined not more than five hundred dollars (\$500) and be imprisoned not less than five (5) or more than ten (10) years. For a third or subsequent offense, or if the offender shall previously have been convicted two⁽²⁾ or more times in the aggregate of any violation of the law of the United States or of any state, territory or district relating to hallucinogenic drugs, the offender shall be fined one thousand dollars (\$1000) and be imprisoned not less than ten (10) or more than twenty (20) years. Except in the case of conviction for a first offense, the imposition or execution of sentence shall not be suspended and probation or parole shall not be granted until the minimum imprisonment herein provided for the offense shall have been served.

(b) Any person who is convicted of the illegal sale, exchange, barter, supplying or giving away of hallucinogenic drugs shall be fined not more than five hundred dollars (\$500) and be imprisoned not less than five (5) or more than ten (10) years. For a second or subsequent offense the penalty shall be the same as that provided for a third offender in subsection (a). For any offense the penalty for which is pro-

vided in this subsection the imposition or execution of sentence shall not be suspended, and probation or parole shall not be granted until the minimum sentence shall have been served."

Further amend by renumbering the sections following accordingly.

Respectfully report as follows: That..... House..... Bill No. 455.....

be amended by amending section 11 (k), line 17, page 17 of the original bill by inserting after the period following the word "board" the following words and punctuation: "Butter, cheese, ice cream and frozen desserts as defined in sections 32-476 through 32-486, R.C.M. 1947 shall be exempt from label statements for artificial flavoring and artificial coloring."

2ND FP PAGE 8 MIMED BILL

be amended as follows:

1. Following line 18, page 35 of the original bill, insert two new sections to read as follows:

"Section 24. It shall be unlawful for any person to manufacture, compound, process, possess, or distribute any drug that is designated by the Federal Act as having a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect, unless authorized to do so by the ~~Secretary of Health~~ ^{Secretary of Health}."

Section 25. (1) Any person who violates section 24 of this act shall upon conviction, be fined not more than two hundred and fifty dollars (\$250) and be imprisoned not less than two (2) or more than five (5) years.

(2) Any person who is convicted of the illegal sale, exchange, delivery, giving away, or otherwise disposing of any of the drugs designated in section 24 of this act to a person who is under the age of twenty-one (21) years shall be fined not more than five hundred dollars (\$500) and be imprisoned not less than five (5) nor more than ten (10) years."

WHEREAS

2. Amend the bill in section 24, line 20, page 35 of the original bill by striking the number "4" and inserting in lieu thereof the number "6".
3. Amend section 25, line 24, page 35 of the original bill by striking the number "5" and inserting in lieu thereof the number "7".

AND, AS AMENDED, DO PASS

House Committee Report form

Revised 3-65

Chairman.

BEST COPY
AVAILABLE

- ☒ DO PASS AS AMENDED
☐ DO NOT PASS
☐ BE CONCURRED IN
☐ BE NOT CONCURRED IN
☐ BE ADOPTED
☐ BE NOT ADOPTED

STANDING COMMITTEE REPORT

February 8 19 57

MR. PRESIDENT: PLEASE:

We, your committee on Public Health, Welfare & Safety

having had under consideration House Bill No. 455

27-101, 27-102, 27-103, 27-104, 27-105, 27-108, 27-109, 27-110, 27-112, 27-113, 27-115, 27-116, 27-117, 27-118, 27-119, 27-120, 90-301.1, and 90-304.

A BILL FOR AN ACT ENTITLED: "AN ACT TO PROVIDE FOR REGULATION OF FOOD, DRUGS, DEVICES, AND COSMETICS BY ADOPTION OF THE UNIFORM STATE FOOD, DRUG AND COSMETIC BILL; REVISING EXISTING LAWS PERTAINING TO FOOD AND DRUG CONTROL; AND REPEALING SECTIONS 27-101, 27-102, 27-103, 27-104, 27-105, 27-108, 27-109, 27-110, 27-112, 27-113, 27-115, 27-116, 27-117, 27-118, 27-119, 27-120, 90-301.1, AND 90-304, REVISED CODES OF MONTANA, 1947."

Respectfully report as follows: That House Bill No. 455 be amended as follows:

(1) Section 11 (k), line 17, page 17 of the original bill — insert after the period following the word "board" the following words and punctuation: "Butter, cheese, ice cream and frozen desserts as defined in sections 32-476 through 32-486, R.C.M. 1947 shall be exempt from label statements for artificial flavoring and artificial coloring."

(2) Following line 19, page 35 of the original bill, insert two new sections to read as follows:

"Section 24. Hallucinogenic Drugs—Prohibitions. It shall be unlawful for any person to manufacture, possess, have under his control, sell, purchase, prescribe, administer, dispense or compound any hallucinogenic drug or any preparation which has a physiological effect similar to that produced by any hallucinogenic drug unless authorized so to do by the department or under the provisions of the Federal Act.

"Section 25. Hallucinogenic Drugs—Penalties.

XXXXXX DO PASS (a) Whoever violates any provision of section 24 shall upon conviction be fined not more than two hundred and fifty dollars (\$250) and be imprisoned not less than two (2) or more than five (5) years. For a second offense, or if, in case of a first conviction of violation of any provision of section 24, the offender shall previously have been convicted of any violation of the laws of the United States or of any state, territory or district relating to hallucinogenic drugs, the offender shall be fined not more than five hundred dollars (\$500) and be imprisoned not less than five (5) or more than ten (10) years. For a third or subsequent offense, or if

the offender shall previously have been convicted two (2) or more times in the aggregate of any violation of the law of the United States or of any state, territory or district relating to hallucinogenic drugs, the offender shall be fined one thousand dollars (\$1000) and be imprisoned not less than ten (10) or more than twenty (20) years. Except in the case of conviction for a first offense, the imposition or execution of sentence shall not be suspended and probation or parole shall not be granted until the minimum imprisonment herein provided for the offense shall have been served.

(b) Any person who is convicted of the illegal sale, exchange, barter, supplying or giving away of hallucinogenic drugs shall be fined not more than five hundred dollars (\$500) and be imprisoned not less than five (5) or more than ten (10) years. For a second or subsequent offense the penalty shall be the same as that provided for a third offender in subsection (a). For any offense the penalty for which is provided in this subsection the imposition or execution of sentence shall not be suspended and probation or parole shall not be granted until the minimum sentence shall have been served."

Further amend by renumbering the sections following accordingly.

And, as amended

DO PASS

FOR ST. R. J. C. , Chairman

The meeting was called to order by the Chairman, Senator Dussault. All the members of the committee were present.

Appearing before the committee as chief sponsor of House Bill No. 25 was Representative Gilligan from Cascade County. He said that the main purpose of this bill was to insure that a deaf person be not deprived of his rights. Representative Gilligan also appeared before the committee as chief sponsor of House Bills 176 and 337. There was no opposition to any of these three bills.

House Bill No. 394 was taken up by the committee. Representative Worden appeared before the committee as chief sponsor of this bill. Roderic R. Gudgel, representing Montana State Pharmaceutical Association, also appeared before the committee as a proponent of this bill.

House Bill No. 485 was next taken up by the committee. Representative Worden appeared before the committee as chief sponsor of this bill. He told the committee that this bill was drafted by Dean Sullivan, of the University of Montana Law School.

Appearing as proponents of House Bill No. 455 were the following: Representative Bollinger, chief sponsor of the bill; C. W. Brink, State Board of Health; Mr. Sloan, Chief of the General Sanitation Section of the State Board of Health; Dr. Anderson of the State Board of Health; and Roderic R. Gudgel, representing the Montana State Pharmaceutical Association. The proponents told the committee that the purpose of this law was to create greater uniformity with the Federal Food, Drug and Cosmetic Act and with similar acts of other states. They said that there was a great need to update our present law to match present day technology of foods, drugs and cosmetics.

House Bill No. 24 was then considered by the committee. Appearing before the committee in behalf of this bill were the following: Representative Bollinger, as chief sponsor of the bill; C. W. Brink, of the State Board of Health, and Dr. Anderson, of the State Board of Health.

Appearing before the committee as a proponent of House Bill 491 was Robert Butzerin, a Helena Attorney, representing Sam Chapman. He explained this bill to the committee and submitted a list of proposed amendments.

After consideration of House Bill No. 25, Senator Turnage made a motion, seconded by Senator Hibbs, that House Bill No. 25 be not concurred in. The motion was carried.

House Bill No. 337 was considered by the committee. After consideration, Senator Hibbs made a motion, seconded by Senator Turnage, that House Bill No. 337 be not concurred in. The motion was carried.

After consideration of House Bill No. 485, no action was taken and Senator Gilfeather was appointed as a sub-committee to work on this bill and report at the next meeting.

After consideration of House Bill No. 176, Senator Turnage moved, seconded by Senator Hibbs, that House Bill No. 176 be concurred in. The motion was carried.

House Bill No. 394 was considered by the committee. After consideration, Senator Turnage made a motion, seconded by Senator Rehberg, that House Bill No. 394 be not concurred in. The motion was carried.

House Bill No. 455 was then considered by the committee. Several amendments were proposed by the members and, after consideration of the amendments, Senator Gilfeather made a motion, seconded by Senator Turnage, that the amendments be adopted. The motion was carried. It was then moved by Senator Turnage, seconded by Senator Gilfeather, that House Bill No. 455, as amended, be concurred in. The motion was carried.

After considering House Bill No. 207, Senator Turnage made a motion, seconded by Senator Rasmussen, that House Bill No. 207 be concurred in. The motion was carried.

House Bill No. 24 was considered by the committee. A prepared set of amendments was submitted to the committee for their consideration. After considering these amendments, Senator Turnage made a motion, seconded by Senator Gilfeather, that the amendments be adopted. The motion was carried. Senator Turnage then moved, seconded by Senator Haughey, that House Bill No. 24, as amended, be concurred in. The motion was carried.

After consideration of House Bill No. 81, Senator Dzivi made a motion, seconded by Senator Turnage, that House Bill No. 81 be not concurred in. The motion was carried.

After consideration of House Bill No. 108, Senator Hibbs moved, seconded by Senator Turnage, that House Bill No. 108, be not concurred in. The motion was carried.

Senator McGowan made a motion, seconded by Senator Rehberg, that the meeting be adjourned. The motion was carried.

- ☐ DO PASS
☐ DO NOT PASS
☒ BE CONCURRED IN
☐ BE NOT CONCURRED IN
☐ BE ADOPTED
☐ BE NOT ADOPTED

STANDING COMMITTEE REPORT

February 21 1967

MR. PRESIDENT:

Judiciary

We, your committee on.....

House

455

having had under consideration.....

Bill No.....

A BILL FOR AN ACT ENTITLED: "AN ACT TO PROVIDE FOR REGULATION OF FOOD, DRUGS, DEVICES, AND COSMETICS BY ADOPTION OF THE UNIFORM STATE FOOD, DRUG AND COSMETIC BILL; REVISING EXISTING LAWS PERTAINING TO FOOD AND DRUG CONTROL; AND REPEALING SECTIONS 27-101, 27-102, 27-103, 27-104, 27-105, 27-108, 27-109, 27-110, 27-112, 27-113, 27-115, 27-116, 27-117, 27-118, 27-119, 27-120, 90-301.1, AND 90-304, REVISED CODES OF MONTANA, 1947."

Respectfully report as follows: That.....

House

Bill No. 455

be amended to read as follows:

Amend on page 35, Section 24, lines 23 and 24 of the original bill, being page 40, Section 24, lines 3 through 5 of the printed bill, by striking the following words "or any preparation which has a physiological effect similar to that produced by any hallucinogenic drug" and inserting in lieu thereof the following words: "as defined in the present Federal Act";

further amend on page 35, Section 25, lines 26 through and on page 36, Section 25, lines 1 through 13 of the original bill, being page 40, Section 25, lines 1 through 15 and page 41, Section 25, lines 16 through 31 of the printed bill, by striking Section 25 in its entirety and inserting in lieu thereof the following: "Section 25. Whoever violates any provision of Section 24 shall, upon conviction, be fined not more than one thousand dollars (\$1000) and be imprisoned not more than one (1) year. Whoever commits a second violation of any provision of Section 24 shall, upon conviction, be fined not less than one thousand dollars (\$1000) and be imprisoned not less than five (5) years nor more than ten (10) years."

XXXXXX

and as so amended

BE CONCURRED IN

7. To exercise all other powers incident to the duties enjoined by the provisions of this act.

Disposition
of funds.

Section 3. All moneys paid out by the park commissioners under the provisions of this act shall be by warrant drawn upon the county treasurer, which shall be signed by the county clerk and countersigned by the president, or, in his absence, by the vice-president of the board of park commissioners. All moneys raised by tax for park purposes, or received by the board of park commissioners for the sale of hay, trees, plants, or from the use of or leasing of lands and facilities shall be paid into the county treasury, and the county treasurer shall keep all such moneys in a separate fund to be known as the "park fund." Such board shall have no power to incur liability on behalf of the county in excess of moneys on hand in, or taxes actually levied for, said park fund.

"Park fund."

Meetings—
quorum—
compensation.

Section 4. The board of park commissioners shall hold an annual meeting on the first Monday of May, and a meeting at least once in each month in each year, at such times as the board shall by rule prescribe. Special meetings may also be held at the call of the president, or, in his absence, the vice-president, upon giving to each member of said board at least twenty-four (24) hours' notice in writing of the time and place of holding such meeting. A member of the board by his appearance at a special meeting shall waive the requirement of written notice. A majority of the entire board shall be necessary to constitute a quorum for the transaction of the business of said board. No park commissioner shall receive compensation for his services rendered under the provisions of this act, but the actual and necessary expense incurred by any member of the board while acting under the orders of the board in the transaction of any business in its behalf may be paid upon being allowed and audited by the board. No park commissioner, directly or indirectly, shall be interested in, or benefit by, any contract made by the board or by its authority, or in the furnishing of any supplies for the use of the board. Any park commissioner who shall refuse or neglect, for the period of three (3) consecutive months, to attend the meetings of said board without leave of absence from said board, or who shall fail for the period of twenty (20) days from and after his appointment to qualify as in this act provided, shall be deemed to have vacated his office, and there-

upon his successor may be appointed. All contracts made by said board shall be in the name of the county, and shall be signed by the county clerk and by the president, or, in his absence, by the vice-president, of said board.

Section 5. The board of park commissioners shall, at its first regular meeting in each month, audit and allow all just claims against the county, liability for which shall have been incurred by said board; but no claim shall be audited or paid until an itemized account of such claim in writing, verified by the oath of the claimant or his or its authorized agent, shall have been filed in the office of the clerk of said board; provided, that no order or resolution providing for the payment or expenditure of money, or creating an obligation in excess of the sum of twenty-five dollars (\$25), or authorizing the making of any contract, shall be passed or adopted except by a ye and nay vote, which vote shall be recorded in full in the minutes by the clerk.

Handling claims.

Section 6. No contract of employment will be entered into except in compliance with the Equal Opportunity Act of 1966, and Executive Order of 1966, providing that there be no discrimination in the employment of persons due to race, creed, color or national origin.

Employment
contract
provisions.

Section 7. The park commissioners shall have authority to accept grants or loans from the United States government subject to agreements in conformance to federal laws and regulations relating thereto notwithstanding any provision of this act or other state statutes to the contrary.

Grants or loans.

Section 8. Nothing in this act shall be so construed as to repeal or annul sections 11-901 to 11-988, or 16-1401 through 16-1414, R.C.M. 1947, or any parts or portions thereof.

Saving clause.

Approved: March 2, 1967.

CHAPTER 307

An Act to Provide for Regulation of Food, Drugs, Devices and Cosmetics by Adoption of the Uniform State Food, Drug and Cosmetic Bill; Revising Existing Laws Pertaining to Food and Drug Control; and Repealing Sections 27-101, 27-102, 27-103, 27-104, 27-105, 27-108, 27-

109, 27-110, 27-112, 27-113, 27-115, 27-116, 27-117, 27-118, 27-119, 27-120, 90-301.1 and 90-304, Revised Codes of Montana, 1947.

Be it enacted by the Legislative Assembly of the State of Montana:

"Montana Food
Drug and
Cosmetic Act."

Section 1. This act may be cited as the Montana Food, Drug and Cosmetic Act.

Section 2. For the purpose of this act—

"State Board."

(a) The term "state board" means the Montana state board of health.

"Department."

(b) The term "department" means the Montana state department of health.

"Person."

(c) The term "person" includes individual, partnership, corporation and association.

"Food."

(d) The term "food" means

(1) articles used for food or drink for man or other animals,

(2) chewing gum, and

(3) articles used for components of any such article.

"Drug."

(e) The term "drug" means

(1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and

(3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(4) articles intended for use as a component of any article specified in clause (1), (2) or (3); but does not include devices or their components, parts or accessories.

"Device."

(f) The term "device" (except when used in paragraph (1) of this section and in sections 3(j), 11(f), 15(e) and (o) and 19(o) means instruments, apparatus and

contrivances, including their components, parts and accessories, intended

(1) for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or

(2) to affect the structure or any function of the body of man or other animals.

(g) The term "cosmetic" means

"Cosmetic."

(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and

(2) articles intended for use as a component of any such articles, except that such term shall not include soap.

(h) The term "official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

"Official
compendium."

(i) The term "label" means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this act that any word, statement or other information appearing on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

"Label."

(j) The term "immediate container" does not include package liners.

"Immediate
container."

(k) The term "labeling" means all labels and other written, printed or graphic matter

"Labeling."

(1) upon an article or any of its containers or wrappers, or

(2) accompanying such article.

(1) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is mislead-

Misbranded
articles.

ing, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

"Advertisement."

(m) The term "advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics.

Antiseptics.

(n) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

"New drug."

(o) The term "new drug" means

(1) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof; or

(2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Contaminated with filth."

(p) The term "contaminated with filth" applies to any food, drug, device or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

(q) The provisions of this act regarding the selling of food, drugs, devices or cosmetics, shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession and holding of any such article for sale; and the sale, dispensing and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug or cosmetic establishment.

"Selling" to include.

(r) The term "pesticide chemical" means any substance which, alone, in chemical combination, or in formulation with one or more other substances is an "economic poison" within the meaning of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C., Secs. 135-135k as now enacted or as hereafter amended), and which is used in the production, storage or transportation of raw agricultural commodities.

"Pesticide chemical."

(s) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing.

"Raw agricultural commodity."

(t) The term "food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958 through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include;

"Food additive."

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the Federal Act; the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).

(u)

"Color additive."

(1) The term "color additive" means a material which—

(A) is a dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral or other source, or

(B) when added or applied to a food, drug or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that such term does not include any material which has been or hereafter is exempted under the Federal Act.

"Color."

(2) The term "color" includes black, white and intermediate grays.

(3) Nothing in clause (1) of section 2(u) shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding or otherwise affecting, directly or indirectly the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

"Federal act."

(v) The term "Federal Act" means the Federal Food, Drug and Cosmetic Act, as amended (Title 21 U.S.C. 301 et seq.).

Prohibited acts.

Section 3. The following acts and the causing thereof within the state of Montana are hereby prohibited:

(a) The manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device or cosmetic.

(c) The receipt in commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The sale, delivery for sale, holding for sale or offering for sale of any article in violation of section 12 or 17.

(e) The dissemination of any false advertisement.

(f) The refusal to permit entry or inspection or to permit the taking of a sample, as authorized by section 22.

(g) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same affect signed by, and containing the name and address of the person residing in the state of Montana from whom he received in good faith the food, drug, device or cosmetic.

(h) The removal or disposal of a detained or embargoed article in violation of section 6.

(i) The alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device or cosmetic, if such act is done while such article is held for sale and results in such article being adulterated or misbranded.

(j) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label or other identification device authorized or required by regulations promulgated under the provisions of this act or of the Federal Act.

(k) The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 17, or that such drug complies with the provisions of such section.

(1) In the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be in-

cluded in any package in which that drug is distributed or sold, or such other printed matter as is approved under the Federal Act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this act.

(m)

(1) Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or

(2) Selling, dispensing, disposing of or causing to be sold, dispensed or disposed of or concealing or keeping in possession, control or custody, with intent to sell, dispense or dispose of, any drug, device or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by subsection (1) hereof; or

(3) Making, selling, disposing of or causing to be made, sold or disposed of or keeping in possession, control or custody, or concealing, with intent to defraud, any punch, die, plate or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device or container thereof.

(n) Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the person ordering or prescribing.

(o) The using by any person to his own advantage, or revealing, other than to the state board, or officers or employees of the department, or to the courts when relevant in any judicial proceeding under this act, any information acquired under authority of this act concerning any method or process which as a trade secret is entitled to protection.

Injunctive remedy.

Section 4. In addition to the remedies hereinafter provided the department is hereby authorized to apply to district court for, and such court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from vio-

lating any provision of section 3; irrespective of whether or not there exists an adequate remedy at law.

Section 5. (a) Any person who violates any of the provisions of section 3 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than three (3) months or a fine of not more than two hundred fifty dollars (\$250) or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final, such person shall be subject to imprisonment for not more than six (6) months, or of a fine of not more than five hundred dollars (\$500) or both such imprisonment and fine.

Violation and penalty.

(b) No person shall be subject to the penalties of subsection (a) of this section, for having violated section 3 (a) or (c) if he establishes a guaranty or undertaking signed by and containing the name and address of the person residing in the state of Montana from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this act, designating this act.

Penalties avoided —when.

(c) No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by him of such false advertisement, unless he has refused, on the request of the department to furnish the department the name and post office address of the manufacturer, packer, distributor, seller or advertising agency, residing in the state of Montana who causes him to disseminate such advertisement.

Exemption from act.

Section 6. (a) Whenever a duly authorized agent of the department finds or has probable cause to believe that any food, drug, device or cosmetic is adulterated, or so misbranded as to be dangerous or fraudulent within the meaning of this act, he shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by such agent or the court. It shall be unlawful for

Procedure if probable cause found.

any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission.

Judicial procedure.

(b) When an article detained or embargoed under subsection (a) has been found by such agent to be adulterated or misbranded, he shall petition the justice of peace, police judge or district court in whose jurisdiction the article is detained or embargoed for a libel for condemnation of such article. When such agent has found that an article so detained or embargoed is not adulterated or misbranded, he shall remove the tag or other marking.

(c) If the court finds that a detained or embargoed article is adulterated or misbranded, such article shall after entry of the decree be destroyed at the expense of the claimant thereof, under the supervision of such agent, and all court costs and fees and storage and other proper expenses shall be taxed against the claimant of such article or his agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or processed, has been executed, may by order direct that such article be delivered to the claimant thereof for such labeling or processing under the supervision of an agent of the department. The expense of such supervision shall be paid by claimant. Such shall be returned to the claimant of the article on the representation to the court by the department that the article is no longer in violation of this act, and that the expenses of such supervision have been paid.

Food to be condemned or destroyed.

(d) Whenever the department or any of its authorized agents shall find in any room, building, vehicle of transportation or other structure, any meat, sea food, poultry, vegetable, fruit or other perishable articles which are unsound, or contain any filthy, decomposed or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the department or its authorized agent, shall forthwith condemn or destroy the same or in any other manner render the same unsalable as human food.

Section 7. It shall be the duty of each state attorney or county attorney, to whom the department reports any violation of this act, to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law. Before any violation of this act is reported to any such attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the department or its designated agent, either orally or in writing, in person or by attorney, with regard to such contemplated proceeding.

Attorney general or county attorney to take appropriate action.

Section 8. Nothing in this act shall be construed as requiring the department to report for the institution of proceedings under this act, minor violations of this act, whenever the department believes that the public interest will be adequately served in the circumstances by a suitable written notice of warning.

Written notice of warning —when.

Section 9. Whenever in the judgment of the state board such action will promote honesty and fair dealing in the interest of consumers, the state board shall promulgate regulations fixing and establishing for any food or class of food a reasonable definition and standard of identity, and/or reasonable standard of quality and/or fill of container. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the state board shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. The definitions and standards so promulgated shall conform so far as practicable to the definitions and standards promulgated under authority of the Federal Act or the state board may promulgate by reference the definitions and standards promulgated under authority of the Federal Act.

Promulgation of regulations —when.

Section 10. A food shall be deemed to be adulterated —(a)

Food is adulterated —when.

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2) (A) if it bears or contains any added poisonous or added deleterious substance, other than one which is

(i) a pesticide chemical in or on a raw agricultural commodity;

(ii) a food additive; or

(iii) a color additive, which is unsafe within the meaning of section 13 (a); or

(B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a) of the Federal Act as amended or

(C) if it is or it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Act as amended; provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under section 408 of the Federal Act, and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of section 13 and clause (C) of this section, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of such residue in the processed food when ready-to-eat, is not greater than the tolerance prescribed for the raw agricultural commodity; or

(3) if it consists in whole or in part of a diseased, contaminated, filthy, putrid or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been produced, prepared, packed or held under insanitary conditions, whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome or injurious to health; or

(5) if it is the product of a diseased animal or an animal which has died otherwise than by slaughter, or that has been fed upon the uncooked offal from a slaughterhouse; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) If any substance has been substituted wholly or in part therefor; or

(3) If damage or inferiority has been concealed in any manner; or

(4) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength or make it appear better or of greater value than it is.

(c) If it is confectionery and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, harmless natural wax not in excess of four-tenths of 1 per centum, harmless natural gum and pectin; provided, that this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

(d) If it is or bears or contains any color additive which is unsafe within the meaning of the Federal Act.

Section 11. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

Food is
misbranded
—when.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food for which a definition and standard of identity has been prescribed by regulations as provided by section 9; or if it is an imitation of another food that is not subject to subsection (g) of this section, unless its label bears in type of uniform size and prominence, the word imitation, and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed or filled as to be misleading.

(e) If in package form, unless it bears a label containing

(1) the name and place of business of the manufacturer, packer or distributor;

(2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the state board.

(f) If any word, statement or other information required by or under authority of this act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be, or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 9, unless

(1) it conforms to such definition and standard, and

(2) its label bears the name of the food specified in the definition and standard, and, in so far as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 9 and its quality falls below such standard unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulation as provided by section 9, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless it bears labeling clearly giving

(1) the common or usual name of the food, if any there be, and

(2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings and colorings, other than those sold as such, may be designated as spices, flavorings and colorings without naming each; provided, that to the extent that compliance with the requirements of clause (2) of this paragraph is impractical or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the state board; and provided further that the requirements of clause (2) of this paragraph shall not apply to food products which are packaged at the direction of purchasers at retail at the time of sale, the ingredients of which are disclosed to the purchasers by other means in accordance with regulations promulgated by the state board.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral and other dietary properties as the state board determines to be, and by regulations prescribes as, necessary in order to fully inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring or chemical preservative, unless it bears labeling stating that fact; provided, that the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the state board. Butter, cheese, ice cream and frozen desserts as defined in sections 32-476 through 32-486, R.C.M. 1947, shall be exempt from label statements for artificial flavoring and artificial coloring.

(l) If it is a product intended as an ingredient of another food and when used according to the directions of the purveyor will result in the final food product being adulterated or misbranded.

(m) If it is a color additive unless its packaging and labeling are in conformity with such packaging and

labeling requirements applicable to such color additive prescribed under the provisions of the Federal Act.

Section 12.

Regulations providing for issuance to manufacturers of permits stating conditions.

(a) Whenever the department finds after investigation that the distribution in Montana of any class of food may, by reason of contamination with microorganisms during manufacture, processing or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered commerce, it then, and in such case only, shall promulgate regulations providing for the issuance to manufacturers, processors or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing or packing of such class of food for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations and during such temporary period, no person shall introduce or deliver for introduction into commerce any such food manufactured, processed or packed by any such manufacturer, processor or packer unless such manufacturer, processor or packer holds a permit issued by the department as provided by such regulations.

Suspension and reinstatement of permits.

(b) The department is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the department shall, immediately after prompt hearing and inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit as originally issued or as amended.

Access to factories by members of department.

(c) Any officer or employee duly designated by the department shall have access to any factory or establishment, the operator of which holds a permit from the department for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

Section 13.

(a) Any added poisonous or deleterious substance, any food additive, any pesticide chemical in or on a raw agricultural commodity or any color additive shall, with respect to any particular use or intended use, be deemed unsafe for the purpose of application of clause (2) (A) of section 10 (a) with respect to any food, section 14 (a) with respect to any drug or device, or section 18 (a) with respect to any cosmetic, unless there is in effect a regulation pursuant to subsection (b) of this section limiting the quantity of such substance and the use or intended use of such substance conform to the terms prescribed by such regulation. While such regulation relating to such substance is in effect, a food, drug or cosmetic shall not, by reason of bearing or containing such substance in accordance with the regulation, be considered adulterated within the meaning of clause 1, section 10 (a), section 14 (a) or section 18 (a).

Regulation of quantity of toxic substances used.

(b) The state board, whenever public health or other considerations in the state so require, is authorized to adopt, amend or repeal regulations whether or not in accordance with regulations promulgated under the Federal Act prescribing therein tolerances for any added poisonous or deleterious substances for food additives, for pesticide chemicals in, or on, raw agricultural commodities or for color additives, including, but not limited to, zero tolerances and exemptions from tolerances, in the case of pesticide chemicals in or on raw agricultural commodities, and prescribing the conditions under which a food additive or a color additive may be safely used and exemptions where such food additive or color additive is to be used solely for investigational or experimental purposes, upon its own motion or upon the petition of any interested party requesting that such a regulation be established; and it shall be incumbent upon such petitioner to establish by data submitted to the state board that a necessity exists for such regulation and that its effect will not be detrimental to the public health. If the data furnished by the petitioner is not sufficient to allow the state board to determine whether such regulation should be promulgated, the state board may require additional data to be submitted and failure to comply with the request shall be sufficient grounds to deny the request. In adopting, amending or repealing

Regulation by state board.

regulations relating to such substances the state board shall consider among other relevant factors, the following which the petitioner, if any, shall furnish:

(1) the name and all pertinent information concerning such substance including where available, its chemical identity and composition, a statement of the conditions of the proposed use, including directions, recommendations and suggestions and including specimens of proposed labeling, all relevant data bearing on the physical or other technical effect and the quantity required to produce such effect.

(2) The probable composition of or other relevant exposure from the article and of any substance formed in or on a food, drug, or cosmetic resulting from the use of such substance.

(3) The probable consumption of such substance in the diet of man and animals taking into account any chemically or pharmacologically related substance in such diet.

(4) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such substances for the use or uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data.

(5) The availability of any needed practicable methods of analysis for determining the identity and quantity of

(A) such substance in or on an article,

(B) any substance formed in or on such article because of the use of such substance, and

(C) the pure substance and all intermediates and impurities and,

(6) facts supporting a contention that the proposed use of such substance will serve a useful purpose.

Section 14. A drug or device shall be deemed to be adulterated—(a)

(1) if it consists in whole or in part of any filthy, putrid or decomposed substance; or

Information
required for
amendment
of regulations.

Drug or device
deemed to be
adulterated
—when.

(2) (A) if it has been produced, prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this act as to safety and has the identity and strength and meets the quality and purity characteristics, which it purports or is represented to possess, or

(3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(4) if

(A) it is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the Federal Act or

(B) it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of the Federal Act.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the Federal Act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality or purity therefor set forth in such compendium, if its difference in strength, quality or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharma-

copoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been

(1) mixed or packed therewith so as to reduce its quality or strength; or

(2) substituted wholly or in part therefor.

Section 15. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing

(1) the name and place of business of the manufacturer, packer or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be allowed, in accordance with regulations prescribed by the state board, or issued under the Federal Act.

(c) If any word, statement or other information required by or under authority of this act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statement, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alphaeucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal,

chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substance, which derivative, after investigation, has been found to be and designated as habit forming, by regulations issued by the state board under this act, or by regulations issued pursuant to section 502 (d) of the Federal Act, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(e) (1) If it is a drug, unless its label bears, to the exclusion of any other non-proprietary name (except the applicable systematic chemical name or the chemical formula),

(A) the established name (as defined in subparagraph (2)) of the drug, if such there be; and

(B) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoseine, hyoseyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein: provided that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs: provided further, that to the extent that compliance with the requirements of clause (B) of this subparagraph is impracticable, exemptions shall be allowed under regulations promulgated by the state board, or under the Federal Act.

(e) (2) As used in this paragraph (e), the term "established name," with respect to a drug or ingredient thereof, means

"Established name."

(A) the applicable official name designated pursuant to section 508 of the Federal Act, or

(B) if there is no such name and such drug, or such ingredient, is an article recognized in an official com-

Drug or device
deemed to be
misbranded
—when.

pendium, then the official title thereof in such compendium or

(C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name if any, of such drug or of such ingredient: provided further, that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply.

(f) Unless its labeling bears

(1) adequate directions for use; and

(2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users; provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the state board shall promulgate regulations exempting such drug or device from such requirements: provided further, that articles exempted under regulations issued under section 502 (f) of the Federal Act may also be exempt.

(g) if it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: provided, that the method of packing may be modified with the consent of the department, or if consent is obtained under the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirement of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia:

provided further, that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the department or under the Federal Act to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the regulations issued by the state board or under the Federal Act require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the department shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or

(2) If it is an imitation of another drug; or

(3) If it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

(k) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless

(1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 506 of the Federal Act, and

(2) such certificate or release is in effect with respect to such drug.

(l) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless

(1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the Federal Act, and

(2) such certificate or release is in effect with respect to such drug: provided, that this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d) of the Federal Act. For the purpose of this subsection the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).

(m) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of section 13(b) or of the Federal Act.

(n) In the case of any prescription drug distributed or offered for sale in this state, unless the manufacturer, packer or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer or distributor with respect to that drug a true statement of

(1) the established name, as defined in section 15 (e) (2) of this act,

(2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502 (e) of the Federal Act, and

(3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issued under the Federal Act.

(o) If a trademark, trade name or other identifying mark, imprint or device or another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.

(p) Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling or packaging requirements of

this act, provided that such drugs and devices are being delivered, manufactured, processed, labeled, repacked or otherwise held in compliance with regulations issued by the state board, or under the Federal Act.

Section 16.

Drugs intended
for use by man.

(a) A drug intended for use by man which —

(1) is a habit-forming drug to which section 15 (d) applies; or

(2) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(3) is limited by an approved application under section 505 of the Federal Act or section 17 of this act to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only

(A) upon a written prescription of a practitioner licensed by law to administer such drug, or

(B) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or

(C) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in a drug being misbranded while held for sale.

(b) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 15, except subsections (a), (i) (2) and (3), (k), and (1), and the packaging requirements of subsections (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient and the directions

for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (a) of this section.

(c) The state board may by regulation remove drugs subject to section 15 (d) and section 17 from the requirements of paragraph (a) of this section when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the Federal Act by regulations issued thereunder may also, by regulations issued by the state board, be removed from the requirements of paragraph (a) .

(d) A drug which is subject to paragraph (a) of this section shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription", or "Caution: State Law Prohibits Dispensing Without Prescription." A drug to which paragraph (a) of this section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(e) Nothing in this section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs or marihuana as defined in the applicable federal and state laws relating to narcotic drugs and marihuana.

Section 17.

(a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless

(1) an application with respect thereto has been approved and said approval has not been withdrawn under section 505 of the Federal Act, or

(2) when not subject to the Federal Act, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and

Limitations on
use of new drugs.

prior to selling or offering for sale such drug, there has been filed with the department an application setting forth

(A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

(B) a full list of the articles used as components of such drug;

(C) a full statement of the composition of such drug;

(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug;

(E) such samples of such drug and of the articles used as components thereof as the department may require; and

(F) specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subsection (a) (2) shall become effective on the one hundred eightieth day after the filing thereof, except that if the department finds, after due notice to the applicant and giving him an opportunity for a hearing, that the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) An order refusing to permit an application under this section to become effective may be revoked by the department.

(d) This section shall not apply—

Exemptions.

(1) to a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs, provided the drug is plainly labeled in compliance with regulations issued by the state board or pursuant to section 505 (i) or 507 (d) of the Federal Act, or

(2) to a drug sold in this state at any time prior to the enactment of this act or introduced into interstate

commerce at any time prior to the enactment of the Federal Act; or

(3) to any drug which is licensed under the Virus, Serum and Toxin Act of July 1, 1902 (U.S.C. 1958 ed. title 42 chapter 6A sec. 262); or

(4) to any drug which is subject to section 15(1) of this act.

(e) The provisions of section 2(o) shall not apply to any drug which, on October 9, 1962 or on the date immediately preceding the enactment of this subsection,

(1) was commercially sold or used in this state or in the United States,

(2) was not a new drug as defined by section 2(o) as then in force, and

(3) was not covered by an effective application under section 17 of this act or under section 505 of the Federal Act, when such drug is intended solely for use under conditions prescribed, recommended or suggested in labeling with respect to such drug.

Section 18. **A cosmetic shall be deemed to be adulterated**—(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual. Provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness." And the labeling of which bears adequate directions for such preliminary testing. For the purpose of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid or decomposed substance.

(c) If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have

Cosmetic deemed adulterated when.

become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains a color additive which is unsafe within the meaning of the Federal Act.

Section 19. **A cosmetic shall be deemed to be misbranded**—(a) If its labeling is false or misleading in any particular.

Cosmetic deemed misbranded when.

(b) If in package form unless it bears a label containing

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count: provided, that under clause (2) of this paragraph reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations prescribed by the state board.

(c) If any word, statement or other information required by or under authority of this act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive prescribed under the provisions of the Federal Act. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 18(a)).

Advertisement
deemed false
—when.

Section 20. (a) An advertisement of a food, drug, device or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(b) For the purpose of this act the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia, venereal disease, shall also be deemed to be false, except that no advertisement not in violation of subsection (a) shall be deemed to be false under this subsection if it is disseminated only to members of the medical, dental, or veterinary professions, or appears only in the scientific periodicals of these professions or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices: provided, that whenever the state board determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the state board shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the state board may deem necessary in the interests of public health: provided, that this subsection shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

Authority for the
promulgation of
regulations vested
in state board.

Section 21. (a) The authority to promulgate regulations for the efficient enforcement of this act is hereby vested in the state board. The state board is hereby authorized to adopt by reference the regulations promulgated by the Food and Drug Administration under the Federal Act.

(b) Hearings authorized or required by this act shall be conducted by the state board or such officer, agent or employee as the state board may designate for the purpose.

(c) Before promulgating any regulations contemplated by section 9; 11 (j); 12; 15 (d), (f), (g), (h), (m),

and (p); 16 (c); or 20 (b), the state board shall give appropriate notice of the proposal and of the time and place for a hearing. The regulation so promulgated shall become effective on a date fixed by the state board (which date shall not be prior to ten (10) days after its promulgation). Such regulation may be amended or repealed in the same manner as is provided for its adoption, except that in the case of a regulation amending or repealing any such regulation the state board, to such an extent as it deems necessary in order to prevent undue hardship, may disregard the foregoing provisions regarding notice, hearing or effective date. No hearing will be required for promulgation by reference of those regulations promulgated under the Federal Act.

Section 22. The department or its authorized agents shall have free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices or cosmetics are manufactured, processed, packed, held for introduction into commerce, or to enter any vehicle being used to transport or hold such foods, drugs, devices, cosmetics in commerce, for the purpose:

Department to
have free access
to all facilities.

(a) of inspecting such factory, warehouse, establishment or vehicle to determine if any of the provisions of this act are being violated, and

(b) to secure samples or specimens of any food, drug, device or cosmetic after paying or offering to pay for such sample. It shall be the duty of the department to make or cause to be made examinations of samples secured under the provisions of this section to determine whether or not any provision of this act is being violated.

Section 23. (a) The department may cause to be published from time to time reports summarizing all judgments, decrees and court orders which have been rendered under this act, including the nature of the charge and the disposition thereof.

Reports and
information
regarding food,
drugs, devices
and cosmetics.

(b) The department may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as the department deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section shall be construed to prohibit the department from collecting, reporting and illustrating the results of the investigations of the department.

Hallucinogenic drugs prohibited. Section 24. **Hallucinogenic drugs — prohibitions.** It shall be unlawful for any person to manufacture, possess, have under his control, sell, purchase, prescribe, administer, dispense or compound any hallucinogenic drug as defined in the present Federal Act unless authorized so to do by the department or under the provisions of the Federal Act.

Violation and penalty. Section 25. Whoever violates any provision of section 24 shall, upon conviction, be fined not more than one thousand dollars (\$1000) and be imprisoned not more than one (1) year. Whoever commits a second violation of any provision of section 24 shall, upon conviction, be fined not less than one thousand dollars (\$1000) and be imprisoned not less than five (5) years nor more than ten (10) years.

Severability clause. Section 26. If any provision of this act is declared unconstitutional or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the act and applicability thereof to other persons and circumstances shall not be affected thereby.

Repealing clause. Section 27. **Repeal.** All acts or parts of acts in conflict herewith are hereby repealed and specifically sections 27-101, 27-102, 27-103, 27-104, 27-105, 27-108, 27-109, 27-110, 27-112, 27-113, 27-115, 27-116, 27-117, 27-118, 27-119, 27-120, 90-301.1, and 90-304, Revised Codes of Montana, 1947.

Approved: March 2, 1967.

CHAPTER 308

An Act to Amend Section 25-501, R.C.M. 1947, and Section 93-303, R.C.M. 1947, as Amended, to Increase Salaries of Elected State Officials, Supreme Court Justices and District Court Judges.

Be it enacted by the Legislative Assembly of the State of Montana:

Amending clause. Section 1. That section 25-501, R.C.M. 1947, is amended to read as follows:

Salaries of elected state officials. "25-501. **Salaries of elected state officials.** The annual salaries paid to the various elected officials of the state of Montana shall be as follows:

Governor	\$23,250
Chief justice of the supreme court	\$18,500
Justices of the supreme court, each	\$17,000
Attorney general	\$15,500
State auditor	\$10,500
Superintendent of public instruction	\$13,750
Railroad commissioner	\$10,500
State treasurer	\$10,500
Secretary of state	\$10,500
Clerk of the supreme court	\$ 9,000

Section 2. That section 93-303, R.C.M. 1947, is amended to read as follows: **Amending clause.**

"93-303. **Salaries of district judges.** The annual salary of each district judge shall be *fifteen thousand dollars (\$15,000).*" **Salaries of district judges.**

Section 3. All acts and parts of acts in conflict herewith are hereby repealed. **Repealing clause.**

Approved: March 2, 1967.

CHAPTER 309

An Act Amending Section 32-1629, R.C.M. 1947, as Amended, Making the Transportation of Garbage, Refuse and Debris Unlawful Unless the Vehicle in Which Same Is Transported Is Protected to Prevent the Garbage, Debris or Refuse From Being Blown or Removed From the Vehicle While in Transsit and Providing a Penalty.

Be it enacted by the Legislative Assembly of the State of Montana:

Section 1. 32-1629, R.C.M. 1947, as amended, is amended to read as follows: **Amending clause.**

"32-1629. **Littering highway as misdemeanor—penalty.** Any person who throws, dumps, deposits or causes to be deposited, any garbage, refuse, waste or litter on the **Littering highway a misdemeanor—violation and penalty.**